

JUN - 8 2001

K011494

Summary of Safety and Effectiveness
Liquichek™ Immunology Control

1.0 **Submitter**

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

May 8, 2001

2.0 **Device Identification**

Product Trade Name: Liquichek™ Immunology Control
Common Name: Multi-Analyte Controls, (Assayed and unassayed)
Classifications: Class I
Product Code: 75JJY
Regulation Number: CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek™ Immunology Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K992550

4.0 **Description of Device**

Liquichek™ Immunology Control is prepared from human serum with added serum proteins and stabilizers.
The control is provided in liquid form for convenience.

5.0 **Statement of Intended Use**

Liquichek™ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.

6.0 **Comparison of the new device with the Predicate Device**

The new Liquichek™ Immunology Control claims substantial equivalence to the Liquichek™ Immunology Control currently in commercial distribution (K992550). The new Liquichek™ Immunology Control contains Ferritin, Retinol Binding Protein and Rheumatoid Factor and the current product does not.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Liquichek™ Immunology Control (New Device)	Bio Rad Liquichek™ Immunology Control (Predicate Device)
Similarities		
Intended Use	Liquichek™ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.	Liquichek™ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage (Unopened Frozen)	-10 °C to -20°C until expiration date	-10 °C to -20°C until expiration date
Storage (Unopened Thawed)	2-8° C 90 days.	2-8° C 90 days.
Open Vial Claim	2-8° C for 30 days.	2-8° C for 30 days..
Differences		
	Same analytes as the predicate device with the additional claims for Ferritin, Retinol Binding Protein and Rheumatoid Factor.	Ferritin, Retinol Binding Protein and Rheumatoid Factor are not included.

7.0 **Summary of Performance Data**

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Immunology Control. Product claims are as follows:

- 7.1 Open vial: Once the control is thawed and opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C.
- 7.2 Closed Vial: Once thawed and stored unopened at 2-8°C, all analytes will be stable for 90 days.
- 7.3 Shelf Life: Two years when stored at -10 to -20 °C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN - 8 2001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Donna Chapman
Quality Assurance/Regulatory Affairs Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K011494
Trade Name: Liquichek™ Immunology Control
Regulation Number: 21 CFR § 862.1660
Regulatory Class: I
Product Code: JJY
Dated: May 8, 2001
Received: May 15, 2001

Dear Ms. Chapman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

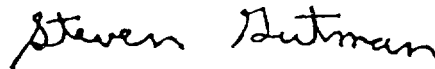
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K011494

Device Name: **Liquichek™ Immunology Control**

Indications for Use:

An assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011494

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____